

# The first-in-human study shows BEAR procedure has similar outcomes to traditional reconstruction

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Today researchers at Boston Children's Hospital announce encouraging Phase I results from a first-of-its-kind study—repairing ACL tears by helping the ligament regrow itself. The results will be presented at the Arthroscopy Association of North America (AANA)/American Orthopaedic Society for Sports Medicine (AOSSM) 2019 Specialty Day on March 16.

In this small, first-in-human study, the team, led by Boston Children's orthopedic surgeons Martha Murray, MD, and Lyle Micheli, MD, got new ACL tissue to form in all 10 experimental trial participants using a procedure called Bridge-Enhanced ACL Repair (BEAR) .

"We wanted to find a way to encourage the ACL to heal itself," says Murray, who invented the procedure. "We hoped we could find a better way than removing the torn ACL and replacing it with perfectly normal tissue from somewhere else, so we started working on a protein-based scaffold."

After decades of laboratory research, the FDA approved a human trial for the BEAR procedure that assessed the safety and early efficacy of the implant used to encourage tissue growth. Of the 20 patients who participated, 10 underwent the BEAR procedure and 10 served as the [control group](#), receiving the standard ACL reconstruction procedure which involves grafting in a piece of tendon taken from elsewhere in the

body.

The BEAR implant is a proprietary bio-engineered sponge and is designed as a bridging scaffold to facilitate healing of the torn ACL. The scaffold is surgically placed between the torn ends of the ACL and some of the patient's own blood is then injected into it. The scaffold soaks up and holds the blood to stimulate healing of the torn ACL.

"At 24 months, nine of the ten repaired subjects and seven of the ten reconstructed patients completed a study visit," says Lyle Micheli, director of the Boston Children's Division of Sports Medicine and lead surgeon on the trial. "There were no graft or repair failures and recovery was similar for both groups, providing us with encouraging outcomes and an exciting road ahead."

Since the completion of the first phase, the team has moved forward with additional phases of the research. The second was a randomized, blinded study of 100 patients, again comparing BEAR procedure with standard reconstruction. A third study will look further at the effects of age on the outcomes of this novel technique

## **ACL Reconstruction Facts**

- Every year approximately 200,000 ACL injuries occur, making ACL surgery one of the most common orthopedic procedures in the United States.
- Although most patients are able to return to sports, the ACL re-tear rate hovers near 20 percent.
- Up to 80 percent of [patients](#) develop arthritis 15 to 20 years after surgery.

Provided by Children's Hospital Boston

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